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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,554	11/21/2003	Michael Rubin	4727-C2-03-DCL	3555

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,554	RUBIN ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the amendment filed 07/28/06 & 08/14/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. By Amendment filed July 28, 2006, claim 1 has been amended and claims 10-11 have been newly added.

2. By Supplemental Amendment filed August 14, 2006, claim 1 has been amended.

3. Claims 1-11 are currently pending for prosecution on the merits.

4. Examiner determines that the amendment does not introduce new matter into the claimed invention since the applicant's amendment for the claim 1 finds support in page 5, line 15 thru page 6, line 5 of the specification and for the claims 10 and 11 finds support in page 6, lines 6-8 and Examples 1-2 of the specification.

Summary of Action

5. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Buch et al. (US 5723106) in view of Clark, Jr. et al. (US 4933172) is not maintained in light of the applicant's amendment and Remarks filed July 28, 2006 and August 14, 2006.

6. Applicant's amendment(s) narrowing the scope of the invention to the specific NSAID, "wherein said at least one NSAID is selected from the group consisting of salicylic cid derivatives, para-aminophenol derivatives, indole and indene acetic acids, heteroaryl acetic acids, propionic acid derivatives, enolic acids, alkanones, apazone and nimesulide, and wherein said salicylic acid derivative is selected from the group consisting of salicyclic acid, acetylsalicylic acid, diflunisal, salsalte, osalazine and sulfasalaine" in claim 1, "wherein said at least one NSAID comprises a propionic acid derivative" in new claim 10 and "wherein said at least one

NSAID comprises acetaminophen" in new claim 11, necessitates a new ground of rejection(s) in this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buch et al. (US 5723106) in view of Singer et al. (US 5294433), and further in view of Giorgetti (US 6194462).

Claims 1-9 read on an oral composition comprising at least one non-steroidal anti-inflammatory agent (NSAID), thymol, methyl salicylate, menthol, a sugar alcohol and a surfactant, wherein said at least one NSAID is selected from the group consisting of salicylic cid derivatives, para-aminophenol derivatives, indole and indene acetic acids, heteroaryl acetic acids, propionic acid derivatives, enolic acids, alkanones, apazone and nimesulide, and wherein said salicylic acid derivative is selected from the group consisting of salicyclic acid, acetylsalicylic acid, diflunisal, salsalte, osalazine and sulfasalaine. Further limitations include "synergistically effective amounts" (claim 2); "about 0.001 to about 2.0 wt. % of said at least one NSAID; about 0.02 to about 0.1 wt% thymol; about 0.03 to about 0.08 wt. % methyl salicylate; about 0.03 to about 0.06 wt. % menthol; and about 0.07 to about 0.11 wt. % eucalyptol" (claim 3), "about 0.1 to about 0.2 wt. % benzoic acid; about 20 to about 55 wt. % of at least one sugar alcohol" (claim 4); "sugar alcohol is selected from the group consisting of sorbitol, xylitol, mannitol, hydrogenated starch hydroslate, and mixtures there" (claim 5), "sugar alcohol is sorbitol" (claim 6), "surfactant selected from the group consisting of anionic, non-ionic and cationic surfactants" (claim 7); "surfactant is a non-ionic surfactant" (claim 8); and "said surfactant is a polaxamer" (claim 9).

Claim 10 read on oral composition comprising at least one non-steroidal anti-inflammatory agent (NSAID), thymol, methyl salicylate, menthol, eucalyptol and wherein said at least one NSAID is a propionic acid derivative.

With respect to 1-10,

Buch teaches an oral care composition comprising about 0.07 to abut 0.11% w/v of said eucalyptol (column 2, lines 36-37); about 0.02 to about 0.06% w/v of said menthol (column 2, lines 39-40); about 0.03 to about 0.08% w/v of said methyl salicylate (column 2, lines 42-43); about 0.03 to about 0.09% w/v of said thymol (column 2, lines 44-46); about 0.1 to about 0.3% w/v of said benzoic acid (column 2, lines 48-49); said sugar alcohol such as sorbitol (column 3, lines 7-8); and said ionic-surfactant such as poloxamer (column 3, line 47, 57 and column 4, line 2). See from column 2, line 21 thru column 5, line 16. Furthermore, the reference teaches the use of said composition for preventing and reducing gingivitis (line 1, column 1, line 26 and Example III).

Singer teaches the use of the anti-inflammatory agent such as ketorolac (which reads on the instantly claimed "heteroaryl acetic acids, see page 5, line 24 of the instant specification), flurbiprofen, ketoprofen, ibuprofen and naproxen (which reads on the instantly claimed "propionic acid derivatives", see page 5, lines 26-27 of the instant specification), indomethacin (which read on the instantly claimed "indole and indene acetic acids'), aspirin (which reads on the instantly claimed "salicylic acid derivative", piroxicam acid in a oral composition containing H-2 antagonist and excipients including from about 0.04 to about 2 wt. % of flavoring agent (e.g., menthol), from about 0 to about 70 wt. % of humectant (e.g., sorbitol), from 0 to about 10% of surfactant (e.g., poloxamer) and benzoic acid or benzoate (column 16, line 51-58; column 17, lines 17-14; column 17, lines 61-66; column 17, line 38 and Examples 7 and 8) for

the treatment of gingivitis, wherein said anti-inflammatory agent is used in dosage amounts from about 0.001% to about 5% by weight (column 19, lines 12-22).

Giorgetti is being supplied as a supplemental reference to demonstrate the art recognition at the time the invention was made in using anti-inflammatory agent in the form of liquids, tinctures and mouthwash solutions in the treatment of periodontial inflammation such as gingivitis (column 1, lines 48-52).

The teaching of Buch differs from the claimed invention in the incorporation of nonsteroidal anti-inflammatory drug (NSAID) such as "salicylic acid derivatives, para-aminophenol derivatives, indole and indene acetic acids, heteroaryl acetic acids, propionic acid derivatives, enolic acids, alkanones, apazone and nimesulide" (claims 1-9), particularly "propionic acid derivative" (claim 10) to said oral care composition. To incorporate such teaching into the teaching of Buch, would have been obvious in view of Singer who teaches the use of the anti-inflammatory agent such as ketorolac, flurbiprofen, ibuprofen, naproxen, indomethacin, aspirin, ketoprofen, piroxicam for treating gingivitis, and further in view of Girogetti who demonstrates the art recognition in using anti-inflammatory agent in the treatment of gingivitis.

Above references in combination make clear that the claimed NSAID such as "salicylic acid derivatives, para-aminophenol derivatives, indole and indene acetic acids, heteroaryl acetic acids, propionic acid derivatives, enolic acids, alkanones, apazone and nimesulide" and the composition comprising thymol, methyl salicylate, menthol, eucalyptol benzoic acid, sugar alcohol (i.e., sorbitol) and a surfactant (i.e., poloxamer) are known to be useful for the treatment of gingivitis. It is obvious to combine compositions each of which is taught by prior art to be

useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component.

As discussed above, the use of thymol, methyl salicylate, menthol, eucalyptol benzoic acid, a sugar alcohol such as sorbiotol and surfactant such as poloxamer in various dosage amounts in oral compositions for treating gingivitis are well recognized in the art. Furthermore, the incorporation of anti-inflammatory agents in an oral composition in combination with the secondary agents (e.g., thymol, methyl salicylate, menthol and eucalyptol) is well recognized in the art. Furthermore, determination of the appropriate dosage amounts of active and inactive ingredients (" about 0.001 to about 2.0 wt. % of said at least one NSAID; about 0.02 to about 0.1 wt% thymol; about 0.03 to about 0.08 wt. % methyl salicylate; about 0.03 to about 0.06 wt. % menthol; and about 0.07 to about 0.11 wt. % eucalyptol", "about 0.1 to about 0.2 wt. % benzoic acid; about 20 to about 55 wt. % of at least one sugar alcohol") for the intended treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed in the prior art. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Regarding claim 10, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species from the Singer's listed antiinflammatories

(total of 9 species), including the claimed propionic acid derivatives such as flurbiprofen, ketoprofen, ibuprofen and naproxen, because an ordinary artisan would have the reasonable expectation that any of the species of drugs known as antiinflammatories taught in Singer would have similar properties.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference.

With respect to claim 2, the modified composition of Buch includes all that is recited in claim 2 except "synergistically effective amounts". However, the mere statement of "synergistically effective amounts" in the claim without showing unexpected results over the prior art is considered an obvious task for the skilled artisan. Since the claimed range of each ingredients overlaps with the prior art range, the combining all the ingredients which is taught by prior to be useful for the same purpose would have arrived at the claimed invention, absence evidence to the contrary.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-9 are properly rejected under 35 USC 103.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buch et al. (US 5723106) in view of Singer et al. (US 5294433), and further in view of Giorgetti (US 6194462) and Rajaiah et al. (US 6509007).

Claim 11 read on oral composition comprising at least one non-steroidal anti-inflammatory agent (NSAID), thymol, methyl salicylate, menthol and eucalyptol, wherein said at least one NSAID is acetaminophen.

The modified teaching of Buch (the combination of Buch et al. (US 5723106) in view of Singer et al. (US 5294433), and further in view of Giorgetti (US 6194462) discussed above as applied to the claims 1-10) includes all that is recited in claim 7 except the use of acetaminophen.

Rajaiah is being supplied as supplemental reference to demonstrate the art recognition (especially in oral composition art) in using acetaminophen as the functional equivalent to other non-steroidal anti-inflammatory agent (NSAID) such as ketorolac, flubiprofen, ibuprofen, naproxen, indomethacin, prioxicam and aspirin (column 7, lines 54-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to select acetaminophen because an ordinary artisan would have the reasonable expectation that any of the species of drugs known as antiinflammatories taught in Rajaiah would have similar properties.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Relevant Prior art of Record

9. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. Please reference to Listermint Mouthwash USPTO Reg. T.M. No. 1 808 737 Registered Dec. 7, 1993 first used in commerce Oct. 31, 1988; Cool Mint Listerine Antiseptic Mouthwash USPTO Reg. T.M. No. 1 728 521 Registered Oct. 27, 1992 first used in commerce; Listermint Mouthwash and Gargle USPTO Reg. T.M. No. 956 233 Registered Mar. 27, 1973 first use in commerce Jan. 7, 1972); US 6132702; US 5942211; and US 5817295.

Commercially available "Coolmint Listerine" contains active ingredients: thymol 0.064%, Eucalyptol 0.092%, methyl salicylate 0.060%, menthol 0.042% and inactive ingredients: water, alcohol (21.6%), sorbitol solution, poloxamer 407, benzoic acid, sodium benzoate, flavor and FD&C Green #3; Commercially available "Listerine Antiseptic" contains active ingredients: thymol 0.064%, Eucalyptol 0.092%, methyl salicylate 0.060%, menthol 0.042% and inactive ingredients: water, alcohol (26.9%), poloxamer 407, benzoic acid, sodium benzoate and caramel; Commercially available "Listerine Mouthwash" contains active ingredients: thymol 0.064%, Eucalyptol 0.092%, methyl salicylate 0.060%, menthol 0.042% and inactive ingredients: water, alcohol (21.6%), sorbitol solution, poloxamer 407, sodium saccharin, benzoic acid, sodium benzoate, zinc chloride and FD&C Blue #1.

USP 6132702, USP 5942211 or USP 5817295 teaches the use of anti-inflammatory agents such as NSAIDs in an oral composition in combination with various secondary agents (e.g., thymol, methyl salicylate, menthol and eucalyptol) for the treatment of gingivitis, plaque, periodontal disease and/or breath malodor.

Response to Arguments

10. Applicant's arguments with respect to claims 1-9 have been fully considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. As discussed above, the applicant's amendment excluding meclofenamic acid taught in the Clark (by positively further limiting "at least one NSAID" as to "salicylic cid derivatives, para-aminophenol derivatives, indole and indene acetic acids, heteroaryl acetic acids, propionic acid derivatives, enolic acids, alkanones, apazone and nimesulide, and wherein said salicylic acid derivative is selected from the group consisting of salicyclic acid, acetylsalicylic acid, diflunisal, salsalte, osalazine and sulfasalaine), which the previous rejection relies upon, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No Claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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